

Food and Drug Administration, HHS

§ 524.1443

no response is evident in 7 days, diagnosis and therapy should be reevaluated.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 53 FR 12512, Apr. 15, 1988; 53 FR 27851, July 25, 1988; 64 FR 404, Jan. 5, 1999]

§ 524.1240 Levamisole.

(a) *Specifications.* The drug contains 200 milligrams of levamisole per milliliter of diethylene glycol monobutyl ether (DGME) solution.

(b) *Sponsor.* See 000061 and 053501 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.350 of this chapter.

(d) *Conditions of use. Cattle*—(1) *Amount.* 2.5 milliliters per 110 pounds (10 milligrams of levamisole per kilogram) of body weight as a single dose topically to the back of the animal.

(2) *Indications for use.* Anthelmintic effective against stomach worms (*Haemonchus*, *Trichostrongylus*, *Ostertagia*), intestinal worms (*Trichostrongylus*, *Cooperia*, *Nematodirus*, *Bunostomum*, *Oesophagostomum*, *Chabertia*), and lungworms (*Dictyocaulus*).

(3) *Limitations.* Conditions of constant helminth exposure may require re-treatment within 2 to 4 weeks after the first treatment. Cattle must not be slaughtered within 9 days following last treatment. Do not administer to dairy animals of breeding age. Do not treat animals before dipping or prior to exposure to heavy rain. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism, and before using in severely debilitated animals.

[52 FR 10887, Apr. 6, 1987, as amended at 53 FR 7504, Mar. 9, 1988; 62 FR 61626, Nov. 19, 1997; 67 FR 78355, Dec. 24, 2002]

§ 524.1376 2-Mercaptobenzothiazole solution.

(a) *Specifications.* The drug contains 1.3 percent 2-mercaptobenzothiazole in a suitable solvent.

(b) *Sponsor.* See 017135 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Apply twice daily to affected area.

(2) *Indications for use.* For dogs as an aid in the treatment of hot spots

(moist dermatitis) and as first aid for scrapes and abrasions.

(3) *Limitations.* Clip hair from affected area before applying. If no improvement is seen within 1 week, consult a veterinarian.

[48 FR 15618, Apr. 12, 1983, as amended at 65 FR 50913, Aug. 22, 2000; 68 FR 33381, June 4, 2003]

§ 524.1443 Miconazole nitrate cream; miconazole nitrate lotion; miconazole nitrate spray.

(a) *Specifications.* (1) The cream contains 23 milligrams of miconazole nitrate (equivalent to 20 milligrams of miconazole base) per gram.

(2) The lotion contains 1.15 percent of miconazole nitrate (equivalent to 1 percent miconazole base).

(3) The spray product consists of a dispensing container, sprayer pump assembly, and lotion which contains 1.15 percent of miconazole nitrate (equivalent to 1-percent miconazole base).

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter for use of cream, lotion, and spray; see No. 051259 in § 510.600(c) of this chapter for use of lotion and spray.

(c) *Conditions of use.* (1) Miconazole nitrate is an antifungal agent for topical treatment of infections in dogs and cats caused by *Microsporum canis*, *Microsporum gypseum*, and *Trichophyton mentagrophytes*.

(2) Apply once daily by rubbing into or spraying a light covering on the infected site and the immediate surrounding vicinity. Continue treatment for 2 to 4 weeks until infection is completely eradicated as determined by appropriate laboratory examination.

(3) Accurate diagnosis of infecting organism is essential. Identify by microscopic examination of a mounting of infected tissue in potassium hydroxide solution or by culture on an appropriate medium.

(4) If no improvement is observed in 2 weeks, reevaluate diagnosis and therapy.

(5) Avoid contact with eyes since irritation may result.

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(6) Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 53 FR 26242, July 12, 1988; 62 FR 55161, Oct. 23, 1997; 62 FR 61626, Nov. 19, 1997]

§ 524.1446 Milbemycin oxime solution.

(a) *Specifications.* Each tube contains 0.25 milliliter of a 0.1 percent solution of milbemycin oxime.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* One tube administered topically into each external ear canal.

(2) *Indications for use.* For the treatment of ear mite (*Otodectes cynotis*) infestations in cats and kittens 4 weeks of age and older. Effectiveness is maintained throughout the life cycle of the ear mite.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[65 FR 13905, Mar. 15, 2000, as amended at 66 FR 13849, Mar. 8, 2001]

§ 524.1451 Moxidectin.

(a) *Specifications.* Each milliliter contains 5 milligrams of moxidectin (0.5 percent solution).

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.426 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use—(1) Amount.* 0.5 milligrams moxidectin per kilogram (2.2 pounds) of body weight.

(2) *Indications for use.* Beef and dairy cattle: For treatment and control of internal and external parasites: gastrointestinal roundworms (*Ostertagia ostertagi* (adult and L4, including inhibited larvae), *Haemonchus placei* (adult and L4), *Trichostrongylus axei* (adult and L4), *T. colubriformis* (adult and L4), *Cooperia oncophora* (adult and L4), *C. pectinata* (adult), *C. punctata* (adult and L4), *C. spatulata* (adult), *C. surnabada* (adult and L4), *Bunostomum phlebotomum* (adult), *Oesophagostomum radiatum* (adult and L4), *Nematodirus helvetianus* (adult and L4)); lungworms (*Dictyocaulus viviparus*, adult and L4); cattle grubs (*Hypoderma bovis*, *H. lineatum*); mites (*Chorioptes bovis*,

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Psoroptes ovis (*P. communis* var. *bovis*)); lice (*Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*, *Bovicola* (*Damalinia*) *bovis*); and horn flies (*Haematobia irritans*). To control infections and to protect from reinfection with *H. placei* for 14 days after treatment, *O. radiatum* and *O. ostertagi* for 28 days after treatment, and *D. viviparus* for 42 days after treatment.

(3) *Limitations.* A withdrawal period has not been established for this product on preruminating calves. Do not use on calves to be processed for veal.

[63 FR 14036, Mar. 24, 1998, as amended at 65 FR 36617, June 9, 2000; 66 FR 46370, Sept. 5, 2001]

§ 524.1465 Mupirocin ointment.

(a) *Specifications.* Each gram contains 20 milligrams of mupirocin.

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Dogs:*

(i) *Indications for use.* Topical treatment of bacterial infections of the skin, including superficial pyoderma, caused by susceptible strains of *Staphylococcus aureus* and *Staphylococcus intermedius*.

(ii) *Limitations.* Apply twice daily. Treatment should not exceed 30 days. Because of potential hazard of nephrotoxicity due to polyethylene glycol content, care should be exercised in treating deep lesions. Safety of use in pregnant or breeding animals has not been determined. Not for ophthalmic use. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[53 FR 39085, Oct. 5, 1988, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 524.1484 Neomycin sulfate ophthalmic and topical dosage forms.

§ 524.1484a Neomycin sulfate ophthalmic ointment.

(a) *Specifications.* Each gram of the ointment contains 5 milligrams of neomycin sulfate equivalent in activity to 3.5 milligrams of neomycin base.

(b) *Sponsor.* See No. 017030 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is intended for use in dogs and cats for